Drug Information Bulletin

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Regulatory Affairs Division (RAD), IPA

India approved manufacturing & marketing of Remdesivir

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Content

Editorial

Entire scientific world are trying to have a weapon to fight the COVID-19 global pandemic and trying to develop vaccine to prevent the disease and to develop a drug for treatment of the infected patients.

It is known from reliable sources that globally about 200 projects and 30 projects in India are going on to develop vaccine against COVID-19. Different groups are trying to develop different types of vaccines which ranges from age old technique to the most modern RNA vaccine. Several companies like- J & J, Sanofi, GSK, Merk etc. in the international level and Indian companies like- Zydus Cadila, Bharat Biotech, Aurobindo etc. are working for development of COVID vaccines. Some of them are in Phase I trial and some of them are moving to Phase II trial. In spite of huge initiative experts are sceptical to develop and marketing a vaccine against COVID-19 very fast.

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A group of scientists unable to confirm benefit of Hydroxychloroquine or Chloroquine in COVID-19 treatment: Lancet

"We are unable to confirm a benefit of Hydroxychloroquine or Chloroquine, when used alone or without a macrolide, on in-hospital outcomes for COVID-19. Each of these drug regimens was associated with decreased in-hospital survival and an increased frequency of ventricular arrhythmias when used for treatment of COVID-19."-stated by authors of a review article published in Lancet on 22nd May 2020.
For details: www.thelancet.com/journal

Benefits of HCQ outweigh risks, if any: Govt. of India

on 28th May reiterated that use of Hydroxychloroquine (HCQ) will continue as prophylactic treatment against Covid-19 in high-risk categories and that this decision has been taken with "responsibility". Niti Aayog member (health) and head of Covid-19 medical management empowered group, V K Paul said the findings of studies conducted in India show "benefits of the drug outweigh risks if any" and therefore, the guidelines issued by the ICMR for use of HCQ are "appropriate".

"We are doing what we are doing with responsibility," Paul said, underlining that Chloroquine is an old medicine with known efficacy and HCQ is even advanced and safer. "We will use it in treatment as per the clinical protocol. We will also revise the guidelines as we keep getting relevant data." The comments come in the wake of many countries including France, Italy and Belgium stopping use of HCQ, after the WHO suspended its use in clinical trials. Paul said WHO was not the only platform where the drug was being tried. Trials on HCQ are going on in many countries. Its effect in tissue culture is well known.
Ref.:
https://health.economictimes.indiatimes.com/news/diagnostics/benefits-of-hcq-outweigh-risks-if-any-govt/76084650

Health Ministry Issues Guidelines on Reuse, Disinfection of Eye Protection Goggles

A single goggle can be worn at least six times as a component of a personal protective equipment (PPE) kit by a healthcare worker, according to the latest guidelines issued by the Union Ministry of Health & Family Welfare (MoH&FW) on the rational use of the special glasses while attending to coronavirus disease (Covid-19) patients or related swab samples
"Goggles may be issued to each healthcare worker, who will decontaminate them after every use. Goggles to be disinfected by users and reused at least five times each, whereby one pair of goggles will suffice for six days. They may use them rationally till their transparency decreases, or they get damaged. The ratio of issue of goggles to coverall is recommended at 1:6," the advisory said.
Goggles are key to a PPE kit, whose components after their use are discarded as bio-medical waste as per the standard operating procedure (SOP). However, the goggles that conform to the prescribed quality specifications of the Bureau of Indian Standards (BIS) can be reused after proper disinfection, the ministry said.
"The purpose of this document is to enable individuals to reuse goggles used by them and allowing an extended use without running the risk of contracting infection," the advisory said.
The ministry has been issuing advisories at regular intervals to guide healthcare workers on how to rationally use their protective gear after the country faced an acute shortage of PPE kits during the initial stages of the viral outbreak, leading to widespread panic and a public outcry.

"We don't face any shortage anymore but a rational use of the protective gear is still advisable. One must not waste the resources just because the requirement is being met. The ministry has been consulting experts and issuing appropriate guidelines on a regular basis, as it is an evolving situation," said a senior government official, requesting anonymity.
The Centre has provided 1.14 and 9 million N-95 masks and PPE kits, respectively, to the states and other central institutions to date.

"We've identified over 100 domestic manufacturers and in about two months have developed a robust industry indigenously, which has a capacity of manufacturing close to 3 lakh masks and PPE kits each daily. It's a remarkable feat. Besides, the country is not dependent on the

import of these items anymore," the official added.

The Union Ministry of Textiles has identified eight laboratories to run a quality control test of the PPE kits manufactured indigenously.

Industry, Research Bodies Warn Of Reckless Use of Disinfectants against Covid-19

Alkali Manufacturers Association of India (AMAI), National Chemical Laboratory, Pune (CSIR-NCL) and the Mumbai-based Institute of Chemical Technology (ICT) have come together to spread awareness on the safe use of disinfectants that is at the center of the on-going fight against COVID-19.

There have been many instances of disinfection chambers being erected in the country which spray a mist of disinfectants on those passing through the chamber which could do more harm than good, the organizations said in a joint statement.

Quoting a World Health Organisation (WHO) advisory, they stated that the use of disinfectants such as sodium hypochlorite is for disinfecting surfaces and not human beings.

"We are privileged to get the support of two leading organisations involved in scientific research who have endorsed our views on safe disinfection after conducting laboratory tests", said Jayantibhai Patel, President AMAI, the representative body of the alkali industry that produces sodium hypochlorite, chlorine, bleaching solution/powder, etc. the major chemicals used for disinfection.

According to Ashwini Kumar Nangia, Director, CSIR-NCL, sodium hypochlorite (NaOCl) or bleach or hypo must be used with utmost precautions as a disinfectant so as to avoid skin contact as it may harm the skin and cause irritation. Eyes should also be protected by using proper goggles/face shields.

He added, "High concentration of disinfectants can increase chemical exposure to users and may also damage surfaces. The diluted disinfectant solution should be uniformly applied to surfaces and allowed to remain wet and untouched for at least one minute for the chemical to inactivate pathogens and kill any microorganisms."

"The Bureau of Indian Standards has classified sodium hypochlorite of 4-6 per cent concentration for household use. This concentration available commercially must be diluted with water by a skilled person to make the solution for disinfection," said Professor A B Pandit, Vice-Chancellor ICT.

CSIR-NCL, ICT Mumbai, and AMAI are jointly suggesting 0.05 per cent (500 ppm) of bleach as a safe concentration for localised direct spray on abiotic surfaces, but excluding general misting and indoor/ outdoor fogging or fumigation. WHO guidelines do not allow the use of any type of mist tunnel, fogging, or fumigation of outdoor spaces.

"Spraying individuals with disinfectants (such as in a tunnel, cabinet, or chamber) is not recommended under any circumstances. This could be physically and psychologically harmful and would not reduce an infected person's ability to spread the virus through droplets or contact", WHO stated.

The three organisations are of the view that 0.1-0.5 per cent (1000 to 5000 ppm) of bleach should be used for wiping/ cleaning surfaces with a cloth. The lower concentration of 0.1 per cent (1000 ppm) is suitable for general-purpose home/ office disinfection and a higher concentration of 0.5 per cent (5000 ppm) for hospitals and resistant pathogens settings.

Source: The Hindu Businessline

NDMA Impurity Findings in Certain Metformin Extended-Release Products

The U.S. Food and Drug Administration is announcing today that agency laboratory testing has revealed levels of the nitrosamine impurity N-Nitrosodimethylamine (NDMA) above the agency's acceptable intake limit in several lots of the extended-release (ER) formulation of metformin, a prescription drug used to control high blood sugar in patients with type 2 diabetes. The agency is in contact with five firms to recommend they voluntarily recall their products. Company recall notices will be posted on FDA's website. There are additional manufacturers of the metformin ER formulation that supply a significant portion of the U.S. market, and their products are not being recalled. The FDA is continuing to work closely with manufacturers to

ensure appropriate testing. Assessments are underway to determine whether metformin ER recalls will result in shortages and the agency will work closely with manufacturers to prevent or reduce any impact of shortages.

"The FDA has strict standards for safety, effectiveness and quality, and the agency makes every effort based on science and data to help keep the U.S. drug supply safe. We understand that patients may have concerns about possible impurities in their medicines, and want to assure the public that we have been looking closely at this problem over many months in order to provide patients and health care professionals with clear and accurate answers," said Patrizia Cavazzoni, M.D., acting director of the FDA's Center for Drug Evaluation and Research. "Now that we have identified some metformin products that do not meet our standards, we're taking action. As we have been doing since this impurity was first identified, we will communicate as new scientific information becomes available and will take further action, if appropriate."

Patients should continue taking metformin tablets even after recalls occur, until they consult with their health care professional who can prescribe a replacement. Patients with type 2 diabetes could face dangerous health risks if they stop taking their prescribed metformin. The FDA recommends that health care professionals continue to prescribe metformin when clinically appropriate; FDA testing has not shown NDMA in immediate release (IR) metformin products (the most commonly prescribed type of metformin). The agency is working with manufacturers of the recalled tablets to identify the source of the NDMA impurity. At this time, the elevated levels of NDMA have been found in some finished-dose tablets of the ER formulation but have not been detected NDMA in samples of the metformin active pharmaceutical ingredient.

The agency is also asking all manufacturers of metformin containing ER products to evaluate the risk of excessive NDMA in their product and to test each batch before it is released into the U.S. market. If testing shows NDMA above the acceptable intake limit, the manufacturer should inform the agency and should not release the batch to the U.S. market.

In late 2019, the FDA announced it had become aware of NDMA in some metformin products in other countries. The agency immediately began testing to determine whether the metformin in the U.S. supply was at risk, as part of the ongoing investigation into nitrosamine impurities across medication types. By February 2020, the agency had identified very low levels of NDMA in some samples, but at that time, no FDA-tested sample of metformin exceeded the acceptable intake limit for NDMA. The FDA has maintained that it would continue with ongoing testing of metformin and other medications, and if any levels of NDMA or other impurities were identified, swift action would be taken.

Recently, the FDA became aware of reports of higher levels of NDMA in certain ER formulations of metformin via a citizen petition filed by a private laboratory. FDA laboratories tested the same metformin lots that the private laboratory found to contain NDMA above the acceptable intake limit. The agency confirmed unacceptable NDMA levels in some, but not all, of those lots. In other instances, our laboratory detected NDMA in lots that the private laboratory did not. The agency also found that the levels of NDMA, when present, were generally lower than reported by the private laboratory. Given FDA scientists' deep experience quantifying these impurities in drugs, the agency is confident in the reliability of the FDA's testing method and results and will continue to take action based on the latest scientific information. The results have also been consistent with the findings of other regulatory agencies' laboratories around the world.

Source: US FDA News Release